IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION - COLUMBUS

UNITED STATES OF AMERICA Plaintiff vs. THOMAS ROMANO, Defendant	Case No. 2:19-cr-202 Judge Michael H. Watson

THE UNITED STATES' MOTIONS *IN LIMINE*

The United States, by and through undersigned counsel, respectfully moves this Court for Orders *in limine* permitting the admission of: (1) evidence related to the overdose deaths of two of Defendant Thomas Romano, M.D.'s ("Dr. Romano") patients, and (2) data regarding Dr. Romano's controlled substance prescribing practices.

I. MOTION *IN LIMINE* TO PERMIT EVIDENCE RELATED TO OVERDOSE DEATHS OF DR. ROMANO'S PATIENTS

Evidence of the overdose deaths of two of Dr. Romano's patients should be admitted because it is intrinsic to the charged offense, it is relevant, and the high probative value of this evidence is not substantially outweighed by the danger of unfair prejudice. *See* Fed. R. Evid. 402, 403.

a. Factual Background

Dr. Romano began treating patient J.P. on December 11, 2015, for chronic pain related to prior motor vehicle accidents. Dr. Romano's medical records as to J.P. indicate that J.P. suffered from pain in his neck, shoulders, thighs, and lower back. Beginning with J.P.'s initial visit with Dr. Romano, Dr. Romano prescribed J.P. a powerful cocktail of the opioids oxycodone and

oxymorphone.[1] Dr. Romano subsequently increased the dosage of these dangerous opioids in February 2016 and again in April 2016.[2] On September 16, 2016, Dr. Romano prescribed J.P. 30 milligrams of oxycodone to be taken five times a day.[3] The morphine milligram equivalent ("MME") for that oxycodone prescription was 225.[4]

According to a report generated by the Belmont County Coroner's Office and eyewitness accounts, during the early evening hours of September 17, 2016, emergency personnel responded to J.P.'s home in response to a call made by J.P.'s parents. Located at the scene was J.P.'s body, as well as money, marijuana, a white powdery substance, and an empty pill bottle for oxycodone prescribed by Dr. Romano, dated September 16, 2016. J.P.'s cause of death was later determined by the Belmont County Coroner's Office to be an overdose of oxycodone. A handwritten note in Dr. Romano's patient file for J.P., dated October 12, 2016, indicated that Dr. Romano had been informed by another patient that J.P. died after falling in his apartment and breaking his neck. J.P. was 42 at the time of his death.

Dr. Romano began treating E.W. on February 23, 2016, for chronic pain related to prior motor vehicle accidents. Dr. Romano's medical records as to E.W. indicate that E.W. suffered

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[1] The prescriptions provided by Dr. Romano on December 11, 2015, correspond with count 30 of the Superseding Indictment.

[2] The prescription provided by Dr. Romano on April 29, 2016, corresponds with count 31 of the Superseding Indictment.

[3] The prescription provided by Dr. Romano on September 16, 2016, corresponds with count 32 of the Superseding Indictment.

[4] MMEs are the amount of morphine an opioid dose is equal to when prescribed. A conversion to MMEs is often used as a gauge of the abuse and overdose potential that is being prescribed at one time to a patient. The Centers for Disease Control have directed that medical providers limit the MME dose they prescribe, as providers "should carefully reassess evidence of individual benefits and risks when considering increasing [an opioid] dosage" to any level greater than or equal to 50 MMEs per day and "should avoid increasing [a] dosage" of opioids greater than or equal to 90 MMEs per day without "carefully justif[ying]" such a decision. CDC Guideline for Prescribing Opioids for Chronic Pain, *available at* https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf (last visited February 16, 2022).

from pain in his neck, the majority of the left side of his body, as well as his right hand and right ankle. Beginning with E.W.'s initial visit with Dr. Romano, Dr. Romano prescribed E.W. a powerful cocktail of controlled substances, including the opioids oxycodone and oxymorphone, as well as the benzodiazepine clonazepam and the muscle relaxer carisoprodol.[5] On April 19, 2017, Dr. Romano prescribed E.W. 30 milligrams of oxycodone to be taken ten times a day, 40 milligrams of oxymorphone to be taken twice a day, and 300 milligrams of the nerve pain medication gabapentin[6] to be taken six times a day.[7] The combined MMEs for the opioid medications prescribed by Dr. Romano to E.W. was 690. On April 27, 2017, E.W. refilled prescriptions from Dr. Romano for 1 milligram of clonazepam (to be taken twice a day) and 350 milligrams of carisoprodol (to be taken four times a day). [8]

During the early morning hours of May 9, 2017, E.W.'s wife, K.W., located an unconscious E.W. on the floor of their home. Emergency personnel was called to E.W.'s residence, but E.W. was later pronounced dead, at the age of 51. Located in E.W.'s bedroom was a plate, razor blade, snorting straw, and syringe. A white powdery residue was observed in E.W.'s nostrils. The State of West Virginia's Office of the Chief Medical Examiner ("OME") determined that E.W. died as a result of fentanyl and oxycodone intoxication. The OME's toxicology report indicated that

[5] The prescriptions provided by Dr. Romano on February 23, 2016 correspond with count 26 of the Superseding Indictment. The government intends to introduce evidence at trial demonstrating that this combination of drugs that Dr. Romano prescribed—an opioid, a benzodiazepine, and a muscle relaxer—is referred to as the "Trinity" by drug seekers because of the potential "high" associated with that combination. When combined, the drugs are synergistic in causing respiratory depression and can collectively result in death.

[6] Gabapentin is not currently designated as a controlled substance by the State of Ohio or the Controlled Substance Act of 1970, although a number of states, such as Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia and West Virginia, do classify it as such.

[7] The prescriptions provided by Dr. Romano on April 19, 2017 correspond with count 27 of the Superseding Indictment.

[8] The combination of drugs Dr. Romano distributed to E.W. in April of 2017 form the Trinity.

E.W.'s blood contained fentanyl, norfentanyl, oxycodone, oxymorphone, and a marijuana metabolite. Dr. Romano's patient file for E.W. contained a handwritten note, dated May 24, 2017, that Dr. Romano was informed that E.W. had died.

Subsequent to the overdose deaths of patient J.P. in September 2016 and E.W. in May 2017, Dr. Romano failed to curb his over-prescribing of opioids and his dangerous practice of concurrently prescribing opioids with other controlled substances to patients, including to a number of the patients whose prescriptions form counts contained in the Superseding Indictment.

b. Argument

As an initial matter, evidence related to the patients' deaths is *res gestae* evidence, as it is inextricably linked to the charged offenses of 21 U.S.C. § 841(a), and the evidence will be offered to establish that the prescriptions which precipitated those deaths were unlawful, in that they were prescribed outside the usual course of professional practice and not for a legitimate medical purpose. *See United States v. Schwartz*, 702 F. App'x 748, 756 (10th Cir. 2017) ("[t]estimony regarding the deceased patients was inextricably connected to the charged offenses because it was offered to help prove that prescriptions written to those patients were unlawful and not consistent with accepted medical norms").

Moreover, evidence of patients' deaths can demonstrate a practitioner's "[w]anton disregard for the drug-abusive tendencies of its patients," establishing that the practitioner "knew that the clinic's patients were misusing their prescriptions, yet the practice continued to prescribe opioids in irresponsible ways." *Id*. "[T]he evidence of these patients' deaths could be considered by the jury when determining whether [the practitioner] knew that his patients were misusing his prescriptions. As we have said, this is one factor that may suggest that [the practitioner] distributed controlled substances without a legitimate medical purpose and outside the usual course of professional practice." *United States v. Bourlier*, 518 F. App'x 848, 855 (11th Cir. 2013).

The matter before the Court is comparable to *United States v. Hofstetter*, 2019 U.S. Dist. LEXIS 211492 (E.D. Tenn. Dec. 9, 2019), which relied significantly upon *Schwartz* and *Bourlier*. In *Hofstetter*, the court determined that evidence of uncharged patients' deaths was admissible where it had a "[d]irect connection to a provider defendant, meaning the deceased patient was prescribed by a provider defendant and died shortly thereafter, often before their next appointment or within thirty (30) days." *Id*. at *15.

The *Hofstetter* court determined that "[e]vidence of such uncharged deaths is relevant and therefore admissible under Rule 402 of the Federal Rules of Evidence." *Id*. The court further found that "evidence of uncharged patient deaths has some tendency to suggest that a provider defendant knew or was deliberately ignorant of the fact that patients might be misusing prescriptions and overdosing." *Id*. (citations omitted). The *Hofstetter* court additionally found that the "[d]efendants' knowledge that patients were misusing prescriptions is 'one factor that may suggest that [the defendants] distributed controlled substances without a legitimate medical purpose outside the usual course of professional practice.'" *Id*. (citing *Bourlier*, 518 F. App'x at 855).

In its analysis pursuant to Fed. R. Crim. 403, the *Hofstetter* court determined that "[e]vidence of deaths of patients prescribed by a particular defendant is highly probative of that defendant's state of mind. . . . Evidence that defendants' patients were dying is probative of whether defendants knew or were deliberately ignorant of the fact that patients were not legitimate pain patients but were seeking pain pills and misusing their prescriptions. Moreover, because this particular category of evidence is defined by a direct and temporal connection between a particular defendant's practice and a specific patient's death, the Court finds that this evidence is of exceptional probative value." *Id*. at *17 (internal citations omitted). As such, the *Hofstetter* court

found that "[t]he high probative value of such evidence [was] not substantially outweighed by the danger of unfair prejudice." *Id*. at *18. Regarding any concerns as to unfair prejudice, the *Hofstetter* court determined that such concerns could be "[m]itigated to some extent by a limiting instruction." *Id*. at *19 (citing *Bourlier*, 518 F. App'x at 856; *see also Schwartz*, 702 F. App'x at 756).

Much like in *Hofstetter*, certain of Dr. Romano's patients overdosed and died, at least in part, as a result of the controlled substances Dr. Romano prescribed to those patients, and within a short time period after receiving the prescriptions.[9] There is also evidence in the patient files for J.P and E.W. that Dr. Romano was made aware of these patients' deaths shortly after they occurred. That evidence is highly probative as to whether Dr. Romano knew or was deliberately ignorant of the fact that his patients were not legitimate pain patients but were seeking pain pills and misusing their prescriptions, and whether the prescriptions were issued without a legitimate medical purpose and outside the usual course of professional practice. As such, the Court should permit evidence as to deaths of patient J.P. and E.W., as well as the circumstances surrounding their deaths.

In addition, evidence of the patients' deaths and the manner in which they occurred would disabuse the jury of any misconceptions as to the status and whereabouts of J.P. and E.W. Evidence as to the deaths of J.P. and E.W. would "[f]oreclose[] any idea that the patients stopped receiving prescriptions from [the practitioner] because [the practitioner] had stopped treating them." *Bourlier*, 518 F. App'x at 855. Furthermore, "[e]vidence of these patients' deaths would have put to rest any idea that they were not called by the government to testify at trial because they only had good things to say about [the practitioner]." *Id*.

[9] J.P. died the day after receiving a prescription for oxycodone from Dr. Romano; E.W. died 20 days after receiving prescriptions for oxycodone and oxymorphone from Dr. Romano.

II. MOTION IN LIMINE TO PERMIT CONTROLLED SUBSTANCE PRESCRIPTION DATA

Evidence of Dr. Romano's controlled substance prescription data across all patients, including for uncharged patients, during the relevant time period, is admissible to show intent, plan, and absence of mistake. *See* Fed. R. Evid. 404(b). This evidence is highly probative of Dr. Romano's intent and whether he issued the charged prescriptions outside the usual course of professional practice and without a legitimate medical purpose, and is not substantially outweighed by the danger of unfair prejudice. *See* Fed. R. Evid. 403.

a. Factual Background

The government plans to call Paul Short ("Mr. Short"), a representative of DEA's Document and Media Exploitation ("DOMEX") analytics division. Mr. Short reviewed Dr. Romano's prescription data monitoring program ("PDMP") data from the states of Ohio, West Virginia, Kentucky, and Indiana. Mr. Short will testify as to the existence of PDMP databases throughout those states, as well as the state laws which require pharmacies operating in those states to report all fills and re-fills of controlled substances in Schedules II through IV. The states require pharmacies to submit accurate data, with that data being compiled and maintained in a central and searchable database. Mr. Short will also testify that these databases allow medical practitioners to check if their patients are receiving controlled substance prescriptions from other doctors, which is a red flag that a patient is an addict or is selling their medication.

In addition to the aforementioned, Mr. Short will testify as to his statistical and analytical review of Dr. Romano's prescribing habits, including red flags identified from that prescribing, such as high doses of opioids and Dr. Romano's combining of those opioids with other controlled substances.

b. Argument

Within the confines of Fed. R. Evid. 404(b), the PDMP data is admissible to show Dr. Romano's intent, his plan or scheme to issue prescriptions without a legitimate medical purpose, and the absence of mistake. "Uncharged prescriptions of controlled substances in enormous quantities, and in dangerous combinations, support a reasonable inference that the underlying prescriptions were issued outside the usual course of professional practice and without a legitimate medical practice. [The practitioner's] practice-wide evidence was therefore probative of his unlawful intent, undermining his defense at trial that the charged prescriptions amounted to 'a few bad judgments.'" *United States v. Lague*, 971 F.3d 1032, 1040 (9th Cir. 2020); *see United States v. Noel*, 2021 U.S. App. LEXIS 33416, *9-10 (6th Cir. 2021) (red flags such as prescriptions written for and filled by out-of-state patients, non-insurance payments at inflated prices, high doses of opioids, and patients traveling long distances to fill prescriptions support a reasonable inference the underlying prescriptions were filled outside the usual course of professional practice); *United States v. Kraynak*, 2021 U.S. Dist. LEXIS 149559, *12-13 (M.D. Pa. Aug. 10, 2021) (PDMP evidence allowed the jury to evaluate the practitioner's prescribing practices as a whole and compare those practices to other physicians within the state, which was important for the jury in evaluating whether the prescriptions were appropriate, or whether they were excessive and outside the usual course of professional practice and without a legitimate medical purpose).

Indeed, the jury "may consider prescription data sets outside those specifically charged in the indictment to determine whether a physician has exceeded 'the legitimate bounds of medical practice' and 'as evidence of a plan, design, or scheme.'" *United States v. Merrill*, 513 F.3d 1293, 1302 (11th Cir. 2008) (citation omitted); *United States v. Katz*, 445 F.3d 1023, 1029 (8th Cir. 2006) (uncharged prescriptions were relevant and admissible under 404(b) as proof of knowledge and

intent); *United States v. Stump*, 735 F.2d 273, 275 (7th Cir. 1984) (evidence of large number of prescriptions written by defendant but not charged in the indictment were admissible under 404(b) as proof of intent); *United States v. Harrison*, 651 F.2d 353, 355 (5th Cir. 1981) (in considering whether the defendant exceeded legitimate medical practice, "[p]rescriptions issued at other times were admissible as evidence of plan, design or scheme"). The broader data is essential to show that Dr. Romano was not, for example, deceived by manipulative patients in the charged counts that simply fooled him into over-prescribing controlled substances, or that he just made a few bad judgments.

Instead, much like in comparable circumstances in *Lague* and *Kraynak*, Dr. Romano's PDMP data is probative of Dr. Romano's unlawful intent and whether the prescriptions issued were excessive and therefore outside the usual course of professional practice and without a legitimate medical purpose, outweighing any danger of unfair prejudice to Dr. Romano. The PDMP data is damaging to Dr. Romano, but only if the jury believes that it represents evidence of intent. If the jury does not accept that assertion, then the data will not be damaging to Dr. Romano in any capacity. The PDMP data contains statistics, which are not in themselves inflammatory and will not tend to incite the jury's passion.

Regardless, any concerns as to the PDMP data having an unfairly prejudicial impact upon the jury can be addressed via appropriate jury instructions. *See Kraynak*, 2021 U.S. Dist. LEXIS 149559 at *23; *Noel*, 2021 U.S. App. LEXIS at *6-7.

CONCLUSION

For the foregoing reasons, this Court should grant the government's motions *in limine* and permit evidence of the death of J.P. and E.W. during the trial in this case, as well Dr. Romano's prescribing data.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of February, 2022, I filed the foregoing United States' Motions *in Limine* with the Clerk of Court, and that a true and accurate copy of the foregoing was forwarded via ECF to the defendant's counsel of record.

By: *s/Andrew Barras*

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